IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MARYLAND

IN RE: SMITH & NEPHEW BIRMINGHAM HIP RESURFACING (BHR) HIP IMPLANT PRODUCTS LIABILITY LITIGATION	*	MDL No. 2775 Master Docket No. 1:17-md-2775
	*	JUDGE CATHERINE C. BLAKE
Charles Fondren,	*	
	*	
	*	THA TRACK CASE
v.	*	Civil No. CCB-19-998
	*	
	*	
Smith & Nephew, *et al.*	*	

MEMORANDUM

Pending before the court is Charles Fondren's ("Fondren") motion to remand for lack of complete diversity. *See* 28 U.S.C. § 1447(c). Smith & Nephew, Inc. ("Smith & Nephew") removed this case from the Circuit Court of Leflore County, Mississippi, and contends that this court has jurisdiction under the fraudulent joinder doctrine. For the reasons that follow, the court will grant Fondren's motion to remand. The issues have been fully briefed and no oral argument is necessary. *See* Local Rule 105.6 (D. Md. 2018).

BACKGROUND

On November 4, 2010, Fondren, a Mississippi resident, underwent a total hip arthroplasty for his left hip at Greenwood Leflore Hospital ("Greenwood Hospital") in Greenwood, Mississippi. (Compl. ¶¶ 1, 12, ECF No. 2). Fondren's surgeon used Smith & Nephew's hip implant device components—including the R3 acetabular liner, the R3 shell, and modular femoral heads—in a configuration that had not received premarket approval from the FDA. (*Id.* ¶¶ 12–13, 18, 41).

Fondren alleges that Patrick Davis ("Davis"), a Mississippi citizen and "agent and [sales] representative" for Smith & Nephew "supplied, distributed, sold and/or provided" the Smith & Nephew components that were used in Fondren's total hip arthroplasty. (*Id.* ¶¶ 8, 14).

On May 24, 2018, Fondren had revision surgery because of "chronic and debilitating left hip pain." (*Id.* ¶ 19). On October 1, 2018, Fondren filed suit in the Circuit Court of Leflore County, Mississippi, against Greenwood Hospital, Patrick Davis, Smith & Nephew, Inc., and Smith & Nephew PLC. (Notice of Removal at 1, ECF No. 1-1). Fondren alleged: (1) manufacturers' product liability and failure to warn;(2) negligence, negligent design and manufacturing, and negligent failure to warn; and (3) breach of express and implied warranty of merchantability and fitness. (*Id.* ¶¶ 20–55). The negligence and negligent failure to warn claims are brought against Greenwood Hospital and Davis. (Compl. ¶¶ 44–50, ECF No. 2).

On December 27, 2018, Smith & Nephew removed the case to this court, invoking the doctrine of fraudulent joinder. (Notice of Removal, ECF No. 1-1).

ANALYSIS

Fondren argues that remand is appropriate because complete diversity does not exist. Specifically, Fondren contends that Fondren and defendants Greenwood Hospital and Davis are all citizens of Mississippi for diversity purposes. (Pl. Mem. in Support of Motion for Remand ¶¶ 4–6, ECF No. 8). Smith & Nephew counters that defendants Greenwood Hospital and Davis should be ignored for diversity purposes because they were fraudulently joined. (Def. Opp. to Pl. Motion to Remand at 1–2, ECF No. 14).

To establish fraudulent joinder "the removing party must show either 'outright fraud in the plaintiff's pleading of jurisdictional facts' or that 'there is *no possibility* that the plaintiff would be

able to establish a cause of action against the in-state defendant in state court.'" *Johnson v. American Towers, LLC*, 781 F.3d 693, 704 (4th Cir. 2015) (quoting *Hartley v. CSX Transp., Inc.*, 187 F.3d 422, 424 (4th Cir. 1999)). This is an exceptionally heavy burden that is "more favorable to the plaintiff than the standard for ruling on a motion to dismiss under Fed. R. Civ. P. 12(b)(6)." *Johnson*, 781 F.3d at 704 (quoting *Mayes v. Rapoport*, 198 F.3d 457, 464 (4th Cir. 1999)). The removing party must demonstrate that "the plaintiff cannot establish a claim even after resolving all issues of law and fact in the plaintiff's favor." *Johnson*, 781 F.3d at 704 (quoting *Hartley*, 187 F.3d at 424). A plaintiff's claims against non-diverse defendants "need not ultimately succeed to defeat removal"; rather, the plaintiff "must show only a 'glimmer of hope' of succeeding against the non-diverse defendants." *Johnson*, 781 F.3d at 704 (citing *Marshall v. Manville Sales Corp.*, 6 F.3d 229, 223 (4th Cir. 1993); *Mayes*, 198 F.3d at 466).

Smith & Nephew fails to meet this burden. First, Smith & Nephew argues that Fondren cannot establish any cause of action against Greenwood Hospital or Davis based on the off-label use of the metal-on-metal device because the Food, Drug and Cosmetic Act ("FDCA") "codifies" a physician's right to use a device off-label. (Def. Opp. at 1–2, ECF No. 14). *See* 21 U.S.C. § 396 ("Nothing in this chapter shall be construed to limit or interfere with the authority of a health care practitioner to prescribe or administer any legally marketed device to a patient for any condition or disease within a legitimate health care practitioner-patient relationship."). But Smith & Nephew is mistaken. While the FDCA does not provide a federal cause of action against physicians for off-label use of devices, or "limit or interfere" with a physician's authority to administer medical devices, it does not displace or narrow traditional state-law negligence claims against physicians who breach a duty of care in using a device off-label.[1] And even if the court were to accept Smith

[1] Smith & Nephew has provided no authority for its argument to the contrary.

& Nephew's argument, it has no bearing on the claims brought against Davis, a Smith & Nephew sales representative.

Second, Smith & Nephew argues that Fondren cannot state a claim against Greenwood Hospital or Davis because they are "innocent sellers" under the Mississippi Products Liability Act ("MPLA"). (Def. Opp. at 3, ECF No. 14). *See* Miss. Code § 11-1-63(h); *see also Elliott v. El Paso Corp.*, 181 So.3d 263, 268 (Miss. 2015) ("[T]he MPLA has abrogated products-liability claims based on strict-liability or negligence theories, and the MPLA now provides the roadmap for such claims.").[2] To establish a cause of action under the MPLA, Fondren must demonstrate that the product at issue was defective because it "deviated in a material way from the manufacturer's . . . specifications," or because "it failed to contain adequate warnings or instructions," was "designed in a defective manner" or because it "breached an express warranty or failed to conform to other express factual representations upon which the claimant justifiably relied in electing to use the product." § 11-1-63(a)(i)(1)–(4).

The MPLA further specifies that:

> [T]he seller or designer of a product other than the manufacturer shall not be liable unless[: (1)] the seller or designer exercised substantial control over that aspect of the design, testing, manufacture, packaging or labeling of the product that caused the harm for which recovery of damages is sought; [2] or the seller or designer *altered or modified the product*, and the alteration or modification was a substantial factor in causing the harm for which recovery of damages is sought; or [3] the seller or designer had *actual or constructive knowledge of the defective condition* of the product at the time he supplied the product. It is the intent of this section to immunize innocent sellers who are not actively negligent,

[2] The MPLA does not govern negligence claims against manufacturers and sellers that are unrelated to the product's defects, such as "fraud, misrepresentation, or breach of the implied warranty of merchantability." *Elliot*, 181 So.3d at 269. Arguably Fondren has set forth such a claim by alleging that Greenwood Hospital and Davis failed "to use reasonable care in the advertising, marketing, promotion, supply, [and] sale" of the Smith & Nephew hip-arthroplasty components. (Compl. ¶ 47, ECF No. 2). To the extent such a claim exists, Smith & Nephew has set forth no credible argument to explain why Fondren would have no possibility of success on the merits.

but instead are mere conduits of a product.

§ 11-1-63(h) (emphasis added). Fondren contends that Davis does not qualify as an "innocent seller" because he altered or modified the product and because he had actual or constructive knowledge that the off-label combination of Smith & Nephew's total hip arthroplasty components was defective. (Pl. Mem. in Support of Motion for Remand ¶¶ 15–19, ECF No. 8). As an exhibit to its briefing, Smith & Nephew includes an affidavit from Davis that denies both actual and constructive knowledge of this defect and denies any alteration or modification of the product. (Davis Aff. ¶¶ 5–9, ECF No. 1-4).

But Fondren has pled plausible factual allegations that suggest Davis had at least constructive knowledge of the product's defective condition, and arguably that Davis adulterated the product by promoting the use of Smith & Nephew's components in a manner that was expressly prohibited by both the FDA and the product's labeling. Specifically, Fondren alleged that the combination of Smith & Nephew components that Davis promoted never received FDA approval and that the metal modular femoral heads were approved by the FDA only for "articulation against the natural acetabulum as the intended use, not in combination with any artificial acetabular cup like the R3." (Compl. ¶¶ 30, 46–47, ECF No. 2). Moreover, Fondren alleges that the combination of components used in Fondren's surgery had produced adverse results requiring revision surgery in many patients before. (*Id.* ¶¶ 46–47). And, in its recall notice, Smith & Nephew conceded that "16 devices distributed in the United States contained incorrect labeling instructions for Use and product label." (Compl. Ex 1 ["Recall"], ECF No. 1-3 at p. 23). *See* Fed. R. Civ. P. 10(c) ("A copy of a written instrument that is an exhibit to a pleading is a part of the pleading for all purposes.").

This suffices to create a factual dispute as to Davis's knowledge that the product was defective "because it deviated in a material way from the manufacturer's . . . specifications," was "designed in a defective manner," and because of defects in the product's warnings or instructions.

See § 11-1-63(a)(i)(1)–(3). Similarly, it presents a factual dispute as to whether Davis adulterated the product by combining the components in a manner that was expressly prohibited by the component's labeling. § 11-1-63(h). In assessing a claim of fraudulent joinder, the court must resolve all issues of fact in the plaintiff's favor. *Johnson*, 781 F.3d at 704; *Schehrer v. Smith & Nephew, Inc.*, 2019 WL 1002419, at *4 (D. Kan. 2019). Accordingly, Smith & Nephew has failed to carry its burden of establishing that Fondren has "no possibility" of success on the merits of his claims against the non-diverse defendants. *See Hartley*, 187 F.3d at 424.

Next, Smith & Nephew argues that all claims brought against Greenwood Hospital and Davis are preempted by federal law. This argument is not persuasive. State-law causes of action are expressly preempted under the Medical Device Amendments of 1976 (the "MDA") only if they impose a safety or efficacy requirement which is different from or adds to an existing federal requirement. *See* 21 U.S.C. § 360k(a); *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 323–24 (2008). And state-law causes of action, so long as they do not exist solely by virtue of the MDA, are not always impliedly preempted. *Buckman Co. v. Plaintiffs' Legal Committee*, 531 U.S. 341, 347–48, 353 (2001); *In re Smith & Nephew Hip Resurfacing (BHR) Hip Implant Products Liability Litigation ["In re BHR"]*, 300 F. Supp. 3d 732, 746–47 (D. Md. 2018). Federal law prohibits the off-label promotion of devices that rises to the level of misbranding or adulterating a product. 21 C.F.R. § 814.80; 21 U.S.C. §§ 331(a) –(b), 351, 352. Similarly, after receiving premarket-approval of a device, a manufacturer may not alter the device without submitting an application to the FDA for supplemental premarket approval. 21 U.S.C. § 360e(d)(5)(A)(i); 21 C.F.R. § 814.39. To the extent Fondren's claims against Davis are premised on a claim that Davis promoted the use of Smith & Nephew's hip arthroplasty components in a combination that was expressly prohibited by the FDA, Fondren's state-law claim parallels federal requirements. Moreover, because

negligence and negligent misrepresentation claims arise out of "'matters of health and safety' historically protected by the state," they are not impliedly preempted under *Buckman. "In re BHR,"* 300 F. Supp. 3d at 745, 747 (citing *Riegel*, 552 U.S. at 330; *Buckman*, 531 U.S. at 352–53); *Houston v. Medtronic, Inc.*, 957 F. Supp. 2d 1166, 1180–81 (C.D. Ca. 2013). Accordingly, Smith & Nephew has not met its burden of establishing that Fondren's claims are preempted.

Finally, Smith & Nephew argues that Fondren failed to plead sufficient factual allegations under Rule 12(b)(6). The court limits its review of Fondren's factual allegations to an analysis of whether Smith & Nephew has carried its burden of establishing fraudulent joinder. To the extent Fondren bases his MPLA claim on a defective design or deviation from the manufacturer's specifications, he has alleged that the particular combination of components used in his total hip arthroplasty never received FDA approval, (Compl. ¶¶ 18, 41), that the FDA prohibited the use of metal modular femoral heads with a metal acetabular, (*id.* ¶ 30), that the metal-on-metal interaction of these components caused harm, (*id.* ¶¶ 17–19, 29), and that Davis promoted this combination of components, (*id.* ¶¶ 8, 14, 29, 47). Fondren further alleges that Smith & Nephew conceded that "16 devices distributed in the United States contained incorrect labeling instructions for Use and product label," that "labeling was not consistent with that cleared by the FDA," and that the modular femoral heads had been used "off-label with a Cobalt Chrome acetabular cup, in a construct that constitutes a [metal-on-metal] bearing," (Recall, ECF No. 1-3 at p. 23–24). Based on these factual pleadings, Fondren has, at least, a "glimmer of hope" of succeeding against the non-diverse defendants. *See Johnson*, 781 F.3d at 704. Accordingly, Smith & Nephew has failed to carry its burden to establish fraudulent joinder.

CONCLUSION

For the reasons stated above, Fondren's motion to remand will be granted. A separate order follows.

8/22/19
Date

Catherine C. Blake
United States District Judge